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07/12/98	07/24/98	ELLEGE	S BCM-03434

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HM12/0818

EXAMINER	
RAILEY, J	
ART UNIT	PAPER NUMBER
1636	15

DATE MAILED:

08/18/99

Please find below a communication from the EXAMINER in charge of this application  
Commissioner of Patents

# Office Action Summary

Application No.  
09/122,384

Applicant(s)  
Elledge et al.

Examiner  
J. Railey

Group Art Unit  
1636



☒ Responsive to communication(s) filed on 19 Jul 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above, claim(s) 21-25, 27-29, and 36 is/are withdrawn from consideration.

☒ Claim(s) 30-35 is/are allowed.

☒ Claim(s) 1-20 and 26 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Applicant's election of Group I, claims 1-20, 26 and 30-35 in Paper No. 14, received 19 July 1999 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 21-25, 27-29 and 36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 14.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-19 of U.S. Patent No. 5,851,808. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application differ in scope from those of the issued patent. The

methods of recombination of nucleic acid constructs as broadly claimed in the instant application are obvious over the claims to specific vectors used in a similar method.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-20 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a "regulatory element" which is a promoter, does not reasonably provide enablement for any "regulatory element" as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

An essential component of applicant's invention is the presence of a promoter in the second nucleic acid construct. This is important because, in the presence of the recombinase, the first and second nucleic acid constructs will recombine such that the "nucleic acid of interest" found in the first nucleic acid construct will come under the transcriptional control of the promoter ("regulatory element") found in the second nucleic acid construct. Regulatory elements may not have all of the properties of a promoter element and function as such. Termination sequences, for example, are regulatory elements, but they are clearly not what is intended by applicant's disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-5 are drawn to embodiments in which the "regulatory element," which is part of the second nucleic acid construct molecule, is claimed to be a "fusion peptide." Proteins are not part of a nucleic acid construct. The claims are simply incorrect.

The claims are free of the prior art for the following reasons. Regarding claims 1-20 and 26, which are embodiments of the invention found in the parent application 08/864,224 [now U.S. Patent 5,851,808], the following was noted in that parent file:

The claims are free of the prior art. The prior art does not teach the nucleic acid constructs claimed, nor the methods for recombination of these constructs. The prior art had described the use of Cre-*lox* vectors for subcloning of DNA fragments. However, none of the prior art vectors comprising *lox* sequences (the sequence-specific recombinase target site) were shown to have a conditional origin of replication on one plasmid for insertion into a second vector comprising *lox* sequences just downstream of a functional promoter element. The recombination of the *lox* sequences in the presence of Cre protein results in the insertion of a gene of interest present in the first plasmid under the control of the promoter found in the second plasmid. Applicant is provided the following references to complete the record, but none are applied in a rejection under 35 U.S.C. 102 or 103: Tucker et al. [U.S. Patent 5,102,797]; Hasan et al. [Gene **150**:51-56 (1994)]; Holt et al. [Gene **133**:95-97 (1993)]; Elledge et al. [Proc. Natl. Acad. Sci. USA **88**:1731-1735 (1991)]; Brunelli et al. [BioTechniques **16**(6):1061-1064 (1994)].

Regarding claims 30-34, the prior art does not teach the use of two site-specific recombinase sites present on each of two nucleic acid constructs, such that the sites will not recombine between

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Art Unit: 1636

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themselves in the same nucleic acid construct. Regarding claim 35, drawn to constructs using the *loxH* recombinase site, this site is newly created by applicant and is not in the prior art. As discussed at page 66 of the specification, this site was generated by changes to the nucleic acid sequence to decrease stem-loop stability and increase ability to express genes introduced following recombination.

Claims 30-35 are allowed.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Art Unit 1636 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number for Art Unit 1636 is (703) 308-4242 or 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. F. Railey, whose telephone number is (703) 308-0281. The examiner can normally be reached on Monday-Thursday, and alternate Fridays, from 8:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached at (703) 308-4003. The fax phone number for informal transmissions to the examiner is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

16 August 1999

**JOHNNY F. RAILEY II, PH.D.**  
**PRIMARY EXAMINER**  
**TECHNOLOGY CENTER 1600**

